

Negative Urine Results after a CMV Positive Screen on the Newborn Dried Blood Spot: A Quality Improvement Initiative

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In 2019 Ontario began screening for congenital cytomegalovirus (cCMV) as a risk factor for hearing loss on the newborn dried blood spot (DBS). Infants who screen positive for cCMV have infection confirmed by urine PCR (gold standard). DBS as a screening modality for cCMV is reported to have suboptimal sensitivity but high specificity, however our population-based screening program experienced a surprising 8% discordant rate between DBS screens and confirmatory urines.

From 2019 to 2023, 56 patients who screened positive on DBS had negative urine results. These discrepant results were investigated on an ad hoc basis by both the screening laboratory and/or infectious diseases physicians. Some discrepant results were determined to be due to DBS card contamination with CMV DNA, and three urine results were falsely negative. Serologic testing of some infants found nonreactive CMV IgG in 28 babies, inferring false positive DBS and these babies were discharged from the program. In 25 of the 56 infants with negative urine results, cCMV could not be definitively ruled out and these babies were offered developmental and audiologic surveillance.

In 2023 a quality improvement initiative was initiated in collaboration with our provincial reference laboratory to perform reflexive testing on the urine samples that were negative by PCR using a commercial assay. This secondary testing of the urine included CMV viral culture, and PCR testing using the Newborn Screening Ontario (NSO) CMV assay. If all reflexive testing was negative, the DBS screen positive result was deemed a false positive.

Sixty-two negative urine samples underwent reflexive testing, and all were concordant with initial urine PCR results. No false negative urine samples were identified. Based on the outcome of this initiative all infants with a negative urine result are now discharged from the program, eliminating the need for both costly and time-consuming surveillance visits.