

Virginia's Hearing Targeted cCMV Screening Program

Rebecca Levorson, M.D. Pediatric Infectious Disease Specialist, INOVA Deepali Sanghani, MPH, CMV Follow Up Coordinator, VDH





Provide

An overview of cCMV

Discuss

• Development of legislation and screening protocols

Review

• The training and education of stakeholders

Explain

The screening program and VDH follow up

Analyze

Lessons learned

Disclosures

We have no financial disclosure or conflicts of interest with the material in this presentation

Cytomegalovirus (CMV)

60-80% humans are infected by adulthood

Transmission:

- Direct contact: Secretions (oral, genitourinary)
- In utero
- Breastmilk
- Transfusion or transplantation

In Utero Transmission Rate

- 30-35% primary maternal infection
- 1-2% maternal reactivation

0.5-1% of all live born infants are infected with CMV at birth







90% Asymptomatic

1 in 5 infants with cCMV will be permanently affected

10% Symptomatic

Up to 25% will develop hearing loss

66% Long-term neurological impairment 35% hearing loss

Long Term Complications of Congenital CMV

in babies

Infection

Developmental and motor delay

Vision loss

Microcephaly

Seizures

Sensorineural Hearing Loss:

- 35-50% of symptomatic cCMV
- 15% of asymptomatic cCMV



When to Screen

congenital Cytomegalovirus (cCMV)

If Any of the Following are Present:

Failed Hearing Screen

Review results of newborn Saliva CMV PCR Screen.

If saliva CMV

PCR screen not

done at birth

facility, send

send Saliva

or Urine CMV

PCR before

21 days of life.

If positive on saliva CMV PCR send Urine CMV PCR before 21 days of life.

Refer to the Assessment and Monitoring of CMV Screening sheet for additional quidance. Mother positive for acute CMV or CMV reactivation during pregnancy

- · Microcephaly (<3%ile HC at birth)
- Intrauterine Growth Restriction (IUGR) (<10%ile for gestational age)
- Unexplained hydrops fetalis
- Intracranial Calcifications on first imaging exam
- Unexplained hepatomegaly or splenomegaly (>1cm below costal margin)
- AST or ALT > 100 U/L or unexplained direct bilirubin of >1mg/dL
- Petechial Rash or Blueberry Muffin Rash
- Leukomalacia, Polymicrogyria,
 Lissencephaly, Schizencephaly, Pachygyria
- Unexplained persistent thrombocytopenia (<100 x 10³/cm³)

Consider URINE CMV PCR (obtain by 21 days of life if possible)

These recommendations are for outpatient cCMV testing.





VDH.virginia.gov/hearing



Physical Exam

? Microcephaly

? SGA/IUGR

? Hepatosplenomegaly

? Petechiae and/or Purpura

? Jaundice

? Failed Newborn Hearing Test

Evaluate Baby

- 1. Urine CMV PCR
- 2. CBC with diff, platelets
- 3. AST, ALT
- 4. Total and Direct Bili
- 5. Head Ultrasound



Timeline



cCMV Workgroup

Included Key Stakeholders

- Audiologist
- Infectious Disease Specialists
- Otolaryngologists
- Neonatologists
- Parents/Family Members
- Hearing Screeners
- Nursing Staff

Develop Legislation and Protocols

- When/how to conduct screening
- Testing Parameters
- Follow up Outpatient

Design Educational materials

• Inform and educate providers and families







Congenital Cytomegalovirus Submitter Form

PATIENT INFORMATION Last Name: CHILD25		SUBMITTER INFORMATION Submitter Name: BON SECOURS ST. MARY'S HOSPITAL		
Date of Birth(mm/dd/yyyy): 00	8/25/2020	City: RICHMOND		
Address: 9514 TEST LN		State: VA Zip code: 23226		
City: HENRICO State	VIRGINIA Zip code: 23231	Phone#: (804) 99999999 Fax#:		
Male ☐ Female ☐ Unknown	MRN#: ADWER2E2334	Contact Name: MARY JANE		

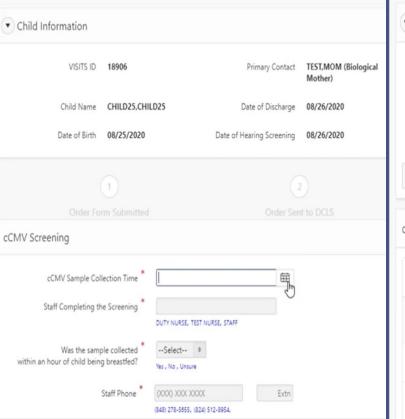
ADDITIONAL INFORMATION

	ADDITIONALIMO	CHATTON .	
Date Collected: 08/26/2020	Time	Collected: 04:00:00 PM	
Specimen Source: X Buccal Swab	Опшина Стини		
Date of Failed Hearing Test: 08/26/2	020	unima (unima di mana)	
External ID#: 18906			
Mother's Name: MOMTEST			
Mother's Date of Birth: 05/25/1977			
Pediatrician Name: AMELIA COU!	NTY - LOCAL HEALTH DEPA	RTMENT	
Pediatrician Phone:			
Pediatrician Address: 16320 CHURO	CH STREET		
City: AMELIA CT HSE	State: VA	Zip Code: 23002	

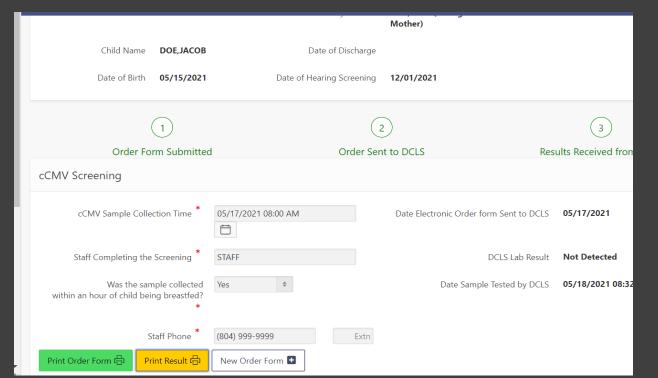
DCLS STATE LAB USE ONLY:

Place applicable DCLS Sample Label(s) in space provided.

EHDI – IS CMV Module



19965	DOE,JANIE	05/15/2021	STAFF	05/18/2021 00:00:00	-	-	-	-	
19967	DOE, JACKSON	05/15/2021	STAFF	05/26/2021 00:00:00	05/26/2021	Not Detected		05/26/2021	
19963	DOE,JOHN	05/15/2021	STAFF	05/26/2021 00:00:00	05/26/2021	Not Detected		05/26/2021	
19965	DOE,JANIE	05/15/2021	STAFF	09/22/2021 09:00:00	10/21/2021	Detected		10/25/2021	
19965	DOE,JANIE	05/15/2021	STAFF	05/18/2021 08:00:00	05/19/2021	Specimen unsatisfactory for evaluation		05/20/2021	
19979	ADAMS,JOHN	05/05/2021	STAFF	05/18/2021 00:00:00	05/19/2021	Detected		05/20/2021	







Commonwealth of Virginia

Division of Consolidated Laboratory Services

600 North 5th St.Richmond, VA 23219 804 648 4480

Report Date: 02/21/2023

Submitter:

FORT BELVOIR COMMUNITY HOSPITAL DEWITT FORT BELVOIR VA 22060

Patient Information

 NAME :
 DOE, JACKSON
 SEX :
 Male

 PATIENT VISITS ID :
 19967
 ETHINICITY :
 UNKNOWN

 DOB :
 05/15/2021
 RACE :

ADDRESS: 2350 HAPPY ST STAFFORD VIRGINIA 22554

Sample Information

DCLS LIMS#:

 SOURCE OF SPECIMEN:
 BUCCAL SWAB
 SUBMISSION DATE:
 05/26/2021

 COLLECTION DATE:
 05/26/2021 12:00:00 AM
 RECEIVED DATE:
 05/26/2021

cCMV TEST RESULTS

RESULT

Cytomegalovirus target DNA Not Detected

Disclaimer: The performance characteristics of this test, as determined by Meridian Bioscience, Inc. and reviewed by the U.S. Food and Drug Administration (FDA) have been validated by the Division of Consolidated Laboratory Services. Results from this test should not be used independently to make decisions regarding the management of patient care.

Comments:

Reviewing Results

Conduct Hospital Training Sessions

- Pid yo Trainings
 - loss and other bland
 - Outreach
 - or other body tissues during the first 21 day.
 - Many children with cCMV have no sympti

Talk to your doctor today about next steps for deten

- Develop of educational resources
- Distribute resources to hospitals and PCPs

Visit our website at www.VDHLiveWell.com for resources, or email us at va_ehdisivdh.virginia.gov



EHDI Team:

CMV Follow Up Coordinator CMV Follow Up Specialist

Key Personnel

DCLS Personnel

Parent Support/ Family Educator

CMV Sample Collection



CONGENITAL CMV SALIVA

Sample Collection Guide

 Obtain a flocked swab - Flexible minitip flocked swab, plastic applicator, sterile, individually packaged.

For example:

- a. Puritan HydraFlock® swab with or without viral transport media.
- · Catalog Number (Peel Pouch): 25-3316-H
- Catalog Number (Dry Tube): 25-3316-H-BT
 Catalog Number (Swab in Conical Tube
- Catalog Number (Swab in Conical Tube with 1 ml UTM); UT116
- b. COPAN FLOQSwabs[®] with or without viral transport media.
- · Catalog Number (Peel Pouch): 503CS01 · Catalog Number (Dry Tube): 553C
- Catalog Number (Swab in Conical Tube with 1 ml UTM): 360C

Or equivalent.



- Confirm that the baby was breastfed > 1 hour prior to collection of the sample.
 - a. For sample collection, baby could be held or in the bassinet.







Wash hands and/or put gloves on, then proceed to opening the sterile flocked swab.



 4a. Introduce the swab between the cheek and the gum in one side of the mouth. Allow to sit for 10-15 seconds.



4b. Move the swab tip to the other side of the mouth for another 10-15 seconds. Make sure the swab appears moistened when removed.



- 5. Remove the swab from the mouth and replace in the holder (paper wrapper, plastic tube or tube with no more than 1mL UTM). The sample is stable 48 hrs at room temperature or 7 days refrigerated.
- 6. Proceed to transport the sample to the





Rejection reasons:

- Sample arrived warm/not cold
- Sample Viral Transport Media (VTM) volume is greater than or less than 1 mL
- Sample was collected when baby was more than 21 days old
- Sample was collected more than 7 days ago
- Labeling error/lack of identification on the sample













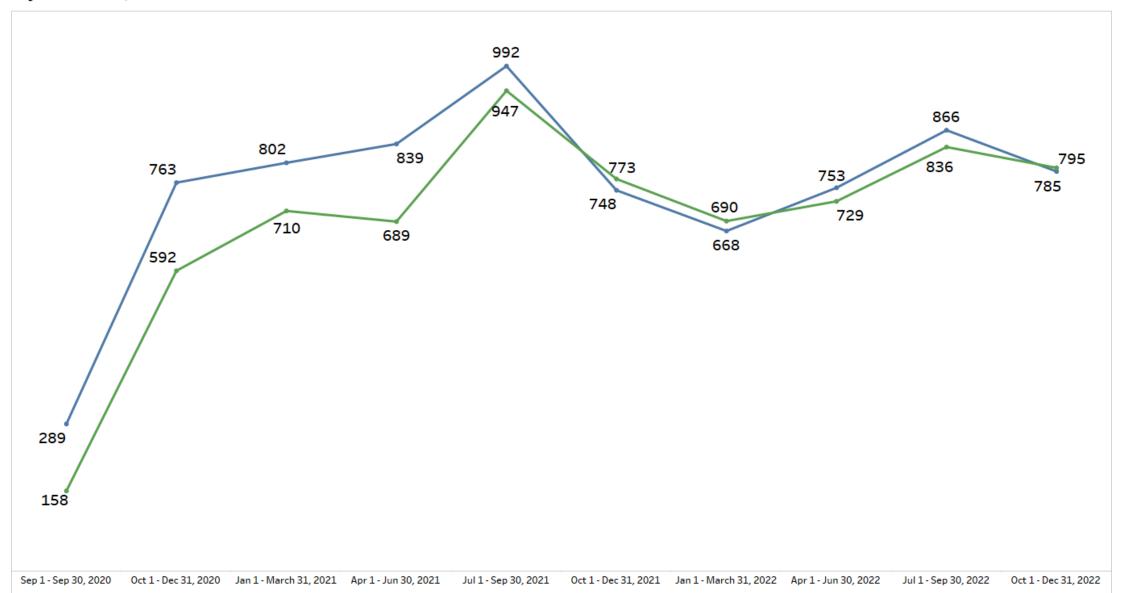
Follow up Recommendations

Saliva Screening Result	Recommendation
Not Detected	Follow recommendations for outpatient hearing screening within 1 month.
Detected	Child should have a urine CMV PCR collected before 21 days of life Follow recommendations for outpatient hearing screening within 1 month.
Unsatisfactory Evaluation	Urine CMV PCR collected before 21 days of life Follow recommendations for outpatient hearing screening within 1 month.
No cCMV test done in hospital	Saliva or urine CMV PCR collected before 21 days of life.

Failed Hearing Screen vs. Screened for cCMV

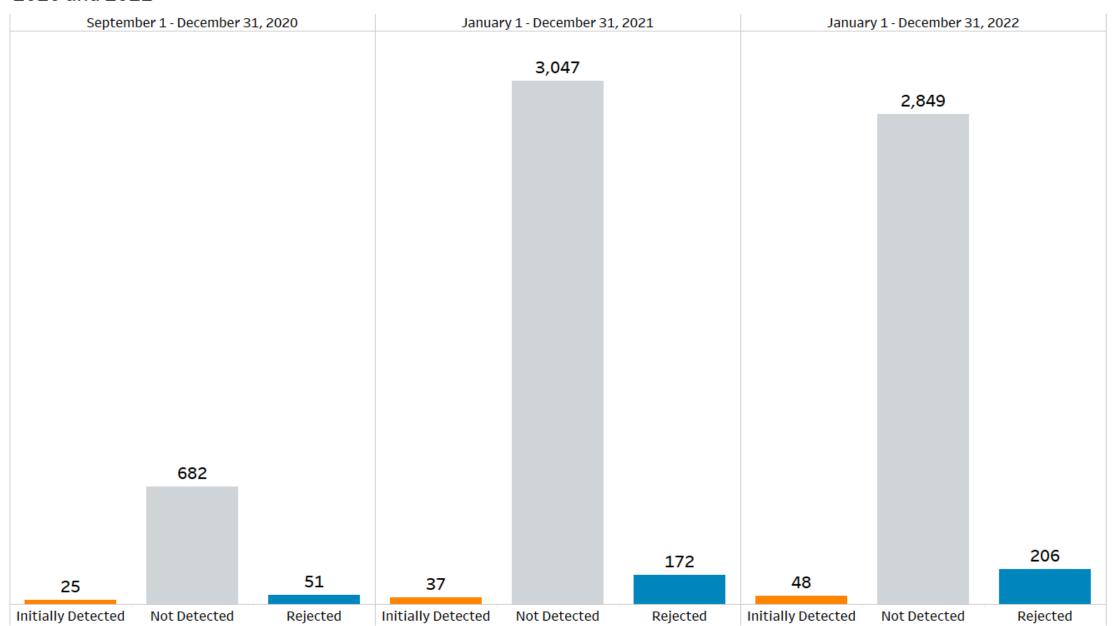


by Quarter, 2020-2022



Results of Initial cCMV Screen 2020 and 2021

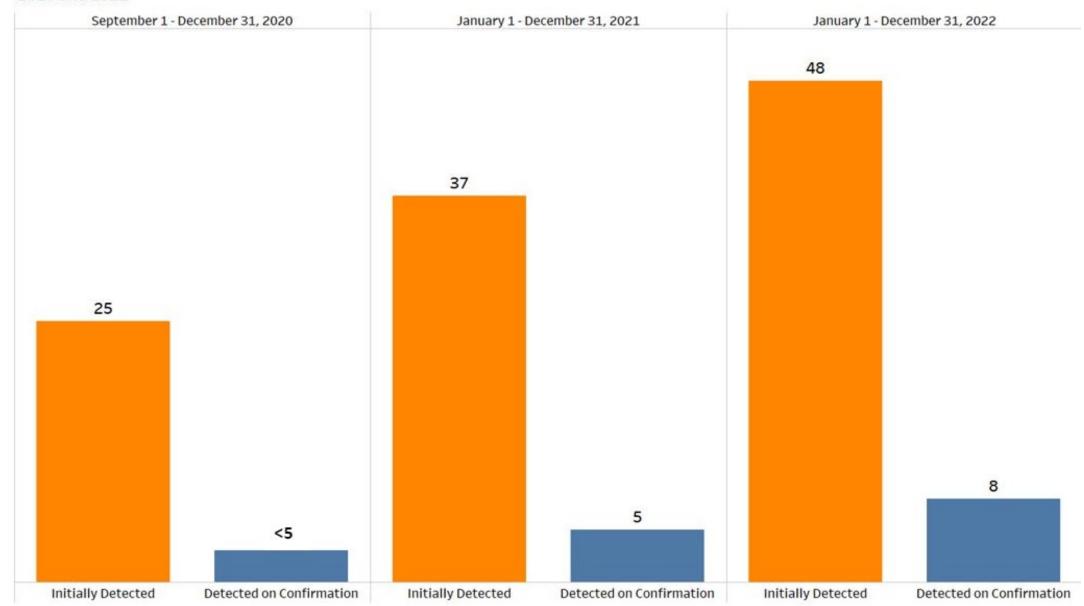




cCMV Initially Detected vs. cCMV Detected on Confirmation

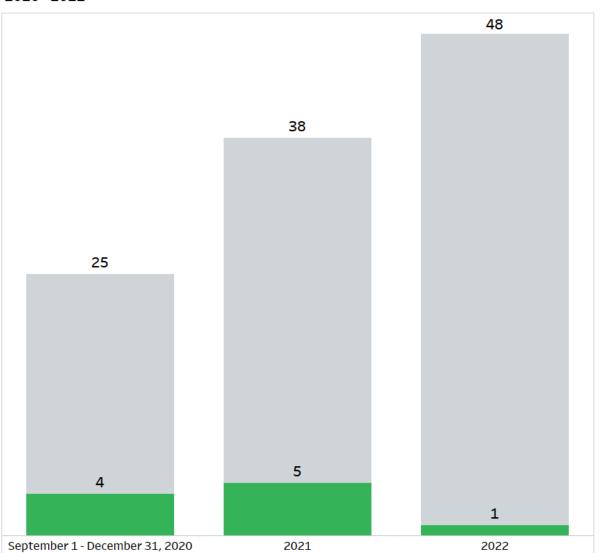


2020 and 2021

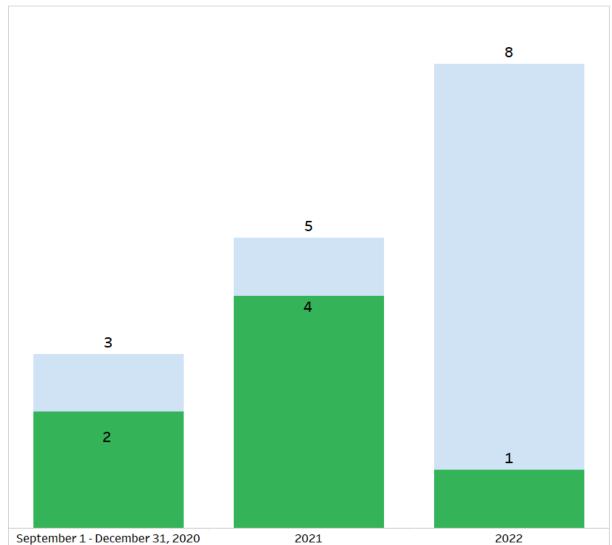




cCMV Initially Detected vs. Hearing Loss 2020 - 2022



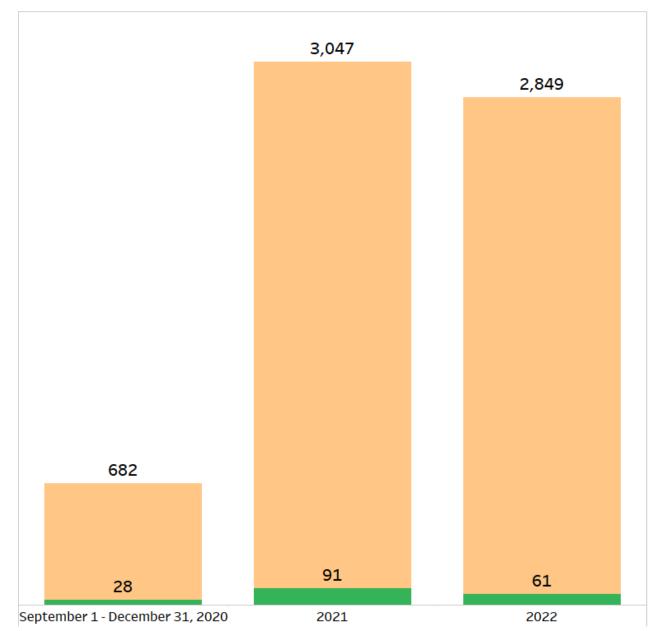
cCMV Detected on Confirmation vs. Hearing Loss 2022

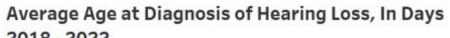


cCMV Not Detected vs. Hearing Loss

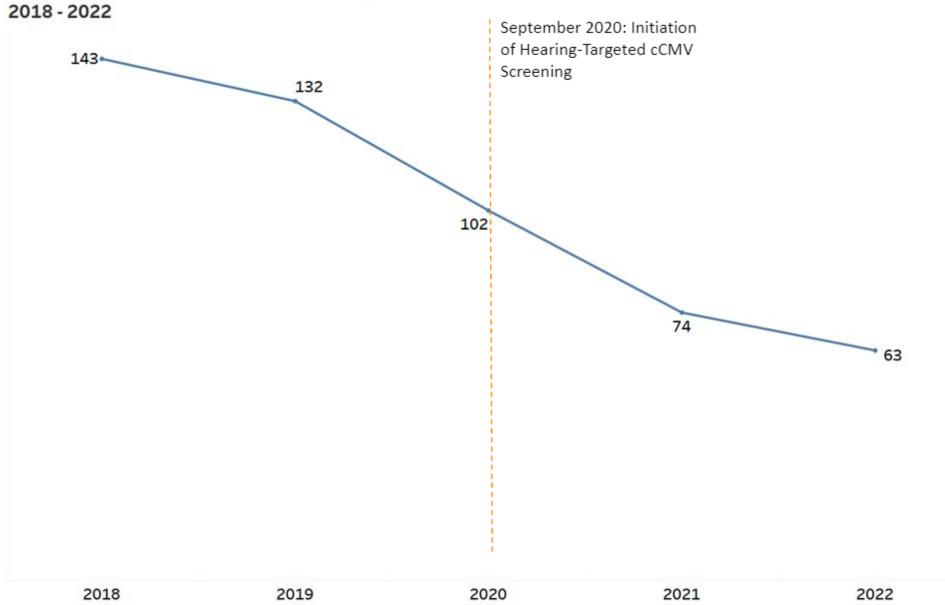














After Implementation

Successes

- Hospital support
- Virtual trainings
- DCLS for all testing

Challenges

- Sample rejection
- High false positive rate
- PCP education and outreach
- Increasing awareness



Physician to Physician Education

- 2019: Key Clinician Stakeholders from all across Virginia crafted the regulations
- 2020: virtual educational sessions through VDH EHDI
- 2020: Pediatric Grand Rounds throughout Virginia
 - all Children's Hospitals had outreach educational sessions
- September 2021: VA AAP/VDH congenital CMV Lecture
- Network of Pediatric Infectious Diseases Physicians based on regions of VA
 - Referral network for clinicians with any clinical cCMV questions











Next Steps











Questions